

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**PLEASE CHARGE ANY FEE DEFICIENCY
TO DEPOSIT ACCOUNT NO. 02-2122**

In re Application Of:)
KOHL et al.) Group Art Unit: 121
SERIAL NO. 748,591) Examiner: J. Fan
FILED: June 14, 1985) Room: 2-9C13
FOR: DIALKOXYPYRIDINES, PROCESSES FOR)
THEIR PREPARATION, THEIR USE AND)
MEDICAMENTS CONTAINING THEM)

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GROUP 120

REQUEST FOR RECONSIDERATION

Honorable Commissioner of Patents
and Trademarks
Washington, D. C. 20231

February 13, 1987

Sir:

Responsive to the Advisory Action (Paper No. 11) of February 3, 1987, Applicants respectfully request reconsideration. They sincerely appreciate the explanation provided by Paper No. 11 but respectfully take issue with the provided rationale. This was discussed briefly with Examiner Fan on February 12, at which time she requested a complete and detailed explanation as to why Applicants regarded the rationale as unjustified. She further indicated that she would carefully review any presented arguments and explanations.

The Declaration executed by Dr. Uwe Krüger on January 27, 1987, is criticized as being "not commensurate with the scope of the claimed subject matter." In support

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of this criticism, it is pointed out that references provide compounds wherein R^3 is ethoxy (the Declaration provides comparisons of fifteen compounds wherein R^3 is methoxy, an adjacent homologue); R^1 is various fluoro substituted C_{1-3} alkyl or chlorodifluoromethyl (fluoro-substituted methyl and ethyl are illustrated for R^1 in the Declaration, and there is no reason to believe that chlorodifluoromethyl would be significantly different than the halogenated alkyls illustrated); R^4 is C_{1-3} alkyl (R^4 is illustrated as methyl in compounds 12 and 14); $R^1 R^1'$ together are ethylenedioxy, methylene-dioxy (methylenedioxy is illustrated by compounds 8 and 9). The preceding parenthetical comments point out the extremely close proximity of the illustrated compounds to anything derivable from the applied art. Reconsideration is respectfully requested. Applicants submit that the showing is truly commensurate in scope with any reasonable interpretation of teachings of applied art. Please note that, from applied art, R^2 and R^4 are defined in exactly the same way and no significance is given to the specific meaning of either. Thus, an illustration in the showing of R^2 as, e.g., methyl would not be expected to be substantially different from a showing with the corresponding compound wherein R^4 is methyl.

Again, Applicants respectfully submit that the showing, when interpreted by one with at least ordinary skill in the art, is clearly commensurate in scope with all significant variations in structure, based on available prior-art teachings. What is even more significant is the completely unexpected differences reflected by the provided data; this is not a question of having data which are relatively close. Most of the data provided is even of a different order of magnitude, and no reason is provided to believe that any significantly different result would be produced by additional comparisons.

Applicants respectfully question the applicability of the opinion for *In re Greenfield and DuPont*, 197 USPQ 227 (CCPA 1978). That case also involved a degradation problem, but that appears to be the limit of the factual similarity. As pointed out in the opinion (at 229):

Appellants have submitted no objective evidence to demonstrate the existence of a degradation problem of 3-isothiazolones and relies solely on their specification. ...As is evident, there is no recitation of the conditions under which these "formulations" were tested, and there is no factual support for the general allegation that unexpected results were obtained. No specific test results regarding these "formulations" are disclosed. Accordingly, Appellants have not rebutted the PTO's *prima facie* case. ...Mere conclusory statements in the specification, unsupported by objective evidence, are entitled to little weight when the PTO questions the efficacy of those statements.

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In the instant case, Applicants have clearly supported the degradation involved in their Declaration. In the same Declaration they have provided comparative test data with regard to seven diversely different compounds of their claimed invention, as compared with eight prior-art counterparts, which are the most closely related reference compounds. All of the basic types of claimed compounds have been compared with their most closely related prior art counterparts. There is no reason to believe that any specifically-selected non-illustrated substituent would produce a result different from those illustrated in the Declaration.

Although the treatment of Claim 23 is a minor issue compared with the foregoing, the PTO recognizes that Claim 22 defines a medicament composition which is an essential and crucial subcombination of the composition called for by Claim 23; furthermore, the composition of Claim 23 relies for patentability on the details of the composition of Claim 22. Reference in this regard is respectfully made to MPEP 806.05(c) which states:

To support a requirement for restriction, both two-way distinctness and reasons for insisting on restriction are necessary.

If it can be shown that a combination, as claimed

- 1) does not require the particulars of the

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subcombination as claimed for patentability (to show novelty and unobviousness), and

2) the subcombination can be shown to have utility either by itself or in other and different relations, the inventions are distinct. When these factors cannot be shown, such inventions are not distinct.

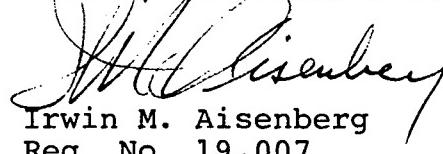
In Paper No. 11 all the PTO has alleged is that the "restriction is proper since the subcombination has other utilities such as insecticides." The other requirement for restriction under the prevailing circumstances has inadvertently been overlooked.

Again, the compounds illustrated in the Declaration are either adjacent homologues or extremely closely related analogues of all of the contemplated compounds. Further, with regard to Claims 26 and 27, unexpected properties have been clearly demonstrated (compounds 2 and 5 in the Declaration). Under the circumstances, it is not understood why the rejection of these claims has been maintained.

In view of the preceding remarks, further and favorable reconsideration of the entire adverse holding is in order and is respectfully solicited.

Respectfully submitted,

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